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IN THE

Supreme Court of the United States

CITIZENS FOR HEALTH, *et al.*,
Petitioners,

v.

MICHAEL O. LEAVITT, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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BRIEF OF LEONARD MORSE, M.D., GUENTER L. SPANKNEBEL, M.D., WAYNE B. GLAZIER, M.D., GRAHAM L. SPRUIELL, M.D., AND ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED

1. May a lower federal court ignore Supreme Court precedent and invent its own "State Action Doctrine"?

2. If not:

   a. May Congress add to the requirements of the Presentment Clause by legislatively restricting its own time to pass a law?

   b. May an agency or executive department set its own boundaries of congressionally delegated authority?

   c. Does the Constitution authorize the federal government to impair the obligations of physician-patient contracts?

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INTERESTS OF *AMICI CURIAE* [1, 2]

Amicus Leonard Morse, M.D., specializes in internal medicine-infectious diseases. He is a past-Chair of the American Medical Association's Council on Ethical and Judicial

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[1] In compliance with Supreme Court Rule 37.6, this brief was not written in whole or in part by counsel for a party, and no person or entity other than *Amici Curiae* and their counsel has made any monetary contribution to the brief's preparation and submission. The parties consent to the filing of this brief.

[2] Medical records of the members of this Court and their staffs may be at risk to the extent that each individual participates in the "Federal Employees Health Benefits Program. . . ." *See* 42 U.S.C.§1320d(5)(M); 45 C.F.R. §160.103.

Affairs and a past-President of Massachusetts Medical Society ("MMS") and of Boston Medical Library. Dr. Morse is Professor of Clinical Medicine at University of Massachusetts Medical School and Commissioner of Public Health for Worcester, Massachusetts.

Amicus Guenter L. Spanknebel, M.D., privately practices gastroenterology and is also past-President of MMS. He is currently Chair of the History Committee and Vice-Chair of the Judicial Committee of MMS. He is Associate Professor of Medicine at University of Massachusetts Medical School and is Assistant Dean for Continuing Medical Education at University of Massachusetts Medical Center-Memorial Campus. He is also on the faculty of Tufts Medical School and is a Trustee of the Health Foundation of Central Massachusetts.

Amicus Wayne B. Glazier, M.D., privately practices urology. He is Chairman of the Health Foundation of Central Massachusetts and President of the Massachusetts Independent Physicians' Association.

Amicus Graham Spruiell, M.D., privately practices psychiatry and psychoanalysis in Boston and is the Chair of the Faculty at the Psychoanalytic Institute of New England, East, Inc.[3]

Amicus Association of American Physicians and Surgeons, Inc. ("AAPS") is a nationwide non-partisan professional association of thousands of physicians in all types of practices and specialties. Since it was founded in 1943, AAPS has been dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the sanctity of the patient-physician relationship.

Pursuant to § 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. No. 104-

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[3] Doctors Morse, Spanknebel, Glazier and Spruiell submit this brief as individual providers and patients and not on behalf of any other entity.

191, 110 Stat. 1936 *et seq.* (August 21, 1996), the Secretary of the United States Department of Health and Human Services ("HHS") issued health privacy regulations ("Regulations").[4] *Amici* believe the Regulations compromise the trust inherent in the patient-physician relationship and reduce patient candor resulting in increased diagnostic and treatment risks. Under the Regulations, the locus of decision-making regarding access to patient medical records is shifted from the patient to physicians and other covered entities and their business associates.

By eliminating patient consent and authorization for the use and disclosure of patient medical information in most situations, the Regulations ignore principles attributed to Hippocrates more than 2,400 years ago and obliterate the foundation of the medical profession—trust between a patient and his or her physician.

As providers and patients, *Amici* disagree with the substance of the Regulations.[5] However, as *amici curiae*, they

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[4] On November 3, 1999, HHS published proposed health privacy regulations. 64 Fed. Reg. 59918 *et seq.* After an extended comment period, the final health privacy regulations were issued in December 2000 ("Original Regulations"). 65 Fed. Reg. 82462 *et seq.* (December 28, 2000), and became effective on April 14, 2001, 66 Fed. Reg. 12434 (February 26, 2001). Modified health privacy regulations were proposed on March 27, 2002, 67 Fed. Reg. 14776 *et seq.*, and were finalized on August 14, 2002, 67 Fed. Reg. 53182 *et seq.* ("Modified Regulations").

[5] *Amici* consider themselves fiduciaries with respect to patient confidences. They believe the Regulations encourage them as well as all covered entities and their business associates to breach that fiduciary duty. *Aufrichtig v. Lowell*, 85 N.Y.2d 540, 546 (1995) ("The physician-patient relationship thus operates and flourishes in an atmosphere of transcendent trust and confidence and is infused with fiduciary obligations.") (citation omitted). *See generally*, Austin Scott, *The Fiduciary Principle*, 37 Cal. L. Rev. 539 (1949); *Meinhard v. Salmon*, 249 N.Y.458, 464 (1928) (Cardozo, Ch. J.) (Fiduciaries are held to higher standards than others. "Not honesty alone, but the punctilio of an honor the most sensitive, is then the standard of behavior").

direct the Court's attention to the Third Circuit's misapplication of the "State Action Doctrine" and to important constitutional issues that will not be addressed unless that error is corrected. These issues question the power and process by which Congress attempted to authorize the Secretary to issue the Regulations.

Today, patient records may be transmitted worldwide in an instant, often without patient knowledge or consent. An inadvertent or intentional release of patient information could endanger millions of patient records at a time. *See*, "VA: Data on 26.5M veterans stolen", USA Today, May 23, 2006, at A1, col. 4; *see also.*, "Bank Loses Tapes of Records of 1.2 Million With Visa Cards", N.Y.Times, Feb. 26, 2005, at A9, col. 3 (Personal information of about 1.2 million federal employees, including United States Senators, was lost by Bank of America); *see also* 65 Fed. Reg. at 82467. Coupling the rapidly evolving technological landscape with exceptions to the consent requirements for disclosures in connection with "treatment, payment and healthcare operations" creates a recipe for disaster. Once the records are released, it is often too difficult or impossible to reverse the breach of privacy.[6]

Although Congress after Congress attempted to strike a balance between public policy goals and the need to keep personal information private, Congress failed to enact any legislation regarding the disclosure of personal medical information because of the inherent tension between these competing objectives. In 1996, Congress decided to break that legislative deadlock, but did so using a blatantly unconstitutional vehicle, *i.e.* § 264(c)(1) of HIPAA. Through § 264(c)(1), Congress imposed, on itself, a three-year deadline to enact legislation governing medical privacy. Under that provision, Congress directed the Secretary to promulgate

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[6] This is analogous to letting air out of a balloon and then futilely attempting to refill that balloon with the same air molecules. It cannot be done.

medical privacy regulations if Congress failed to enact medical privacy legislation by the deadline. Congress missed that deadline and the Secretary ultimately promulgated the Regulations. By enacting § 264(c)(1), Congress sought to accomplish exactly what the Constitution's first clause does not allow: transferring to an executive department authority to enact legislation upon the failure of the legislative process in Congress. U.S. CONST. Art. 1, § 1 ("All legislative Powers herein granted shall be vested in a Congress of the United States. . . .").

Section 264(c)(1) is an effort to accomplish an unconstitutional end by an unconstitutional means. This section is a revolutionary attempt to spare Congress difficult decisions regarding medical privacy by allowing the Secretary to make decisions instead. It undermines, in fundamental and dangerous ways, the Constitution's mechanism for enacting federal laws. Section 264(c)(1) has taken legislative responsibility from Congress and delegated it to the Secretary. It is an impermissible effort by Congress to delegate to the Secretary its most basic duty—to determine what the law shall be. As such, it radically upsets the constitutionally contemplated process of political compromise within the legislative branch and between the legislative and executive branches. This Court must, in this case, protect Congress from itself, and thereby protect the Nation and its people.

ARGUMENT

I. THE COURT BELOW MISAPPLIED THE "STATE ACTION DOCTRINE" BECAUSE HHS IS A COVERED ENTITY

Although the Third Circuit concedes, "the promulgation of the Amended Rule by the Secretary—is clearly government conduct", Appendix to Petition ("App.") 14a, its "state action" analysis relies on the premise that some "third party actor" is not before the court. *Amici* disagree. As a covered entity, the Secretary is that "third party actor" and he is before

the Court. Furthermore, *Amici* believe the promulgation of the Regulations also establishes sufficient "state action" to allow this case to proceed.

The heart of the Third Circuit's "state action" analysis is contained in the text accompanying footnote 12:

> [T]he injury that Citizens allege is that their "personal health information" is being "*used and disclosed*, without their permission and against their will" *by third parties* . . . To support their claims, Citizens point to privacy notices that they received from private health care providers and pharmacies . . . *Citizens did not challenge any use or disclosure by the Secretary himself*, or urge that the third parties were somehow acting on the Secretary's behalf, before the District Court.

App. 14a (emphasis added)(citation omitted).

This analysis ignores allegation 71 of the Complaint. This allegation clearly refers to all covered entities and their business associates. The Secretary is clearly contemplated by the reference to "all covered entities". Allegation 71 provides:

> . . . Defendant has further violated Plaintiffs' rights under the Fifth Amendment by conferring express authorization and "regulatory permission" upon **ALL COVERED ENTITIES** and their business associates to use and disclose even the most sensitive of Plaintiffs' health information without their permission and against their will, retroactively and prospectively.

First Amended Complaint for Declaratory and Injunctive Relief: Constitutional Claim (emphasis added).

Medicare, Medicaid, and the Indian Health Services Programs are defined as "health plans" under the Administrative Simplification provisions of HIPAA. 42 U.S.C. § 1320d (5) (D, E, & L). *See also*, 45 C.F.R. §164.103. As "health plans", these programs are covered entities under 42 U.S.C. § 1320d-1. Based upon these definitions, this Court must conclude that the actor who caused plaintiffs' injuries, *i.e.* the

Secretary, as opposed to an unnamed third party actor, is before the Court.

Although the Third Circuit created the "third party actor" as a straw man in its "state action" analysis, it ignored the Defendant's role as that "third party actor."[7] As Secretary, Defendant supervises Medicare, Medicaid and Indian Health Services Programs, covered entities with 42.1 million, 44.7 million and 1.6 million enrollees, respectively. United States Department of Health and Human Services, What We Do, *available at* www.hhs.gov/about/whatwedo.html. This makes the Secretary the single largest covered entity, using and disclosing more individually identifiable health information ("IIHI") than anyone else.[8] Unlike a criminal defendant who argues that someone else committed the crime, the Secretary cannot say someone else "acted". He wears two hats in this case—as promulgator of the challenged regulations and as the ultimate "third party actor" *i.e.* covered entity. In either capacity, he is a governmental actor and the "State Action Doctrine" is satisfied.

II. THE SECRETARY LACKS AUTHORITY UNDER §264(C)(1) BECAUSE THAT SECTION VIOLATES THE CONSTITUTION

While the District Court examined the contentions of the parties regarding the scope of authority delegated to the

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[7] The Third Circuit apparently ignored its own findings with respect to justiciability, both with respect to the "injury in fact" and "traceability". The court said: "Citizens alleged injuries are 'fairly traceable' to the Secretary's promulgation of the Privacy Rule. . . ." App. 35a-36a.

[8] Given the extent to which the Secretary is a "third party actor" with respect to these programs, it is unnecessary to analyze the Secretary's role in other federally run health plans covering millions of additional enrollees. Such "health plans" include programs and care provided by the Department of Defense, the Veterans Administration, the Federal Employees Health Benefits Program, and the Civilian Health and Medical Program of the Uniformed Services. 42 U.S.C. § 1320d(5)(I, J, K & M).

Secretary, App. 71a-74a, the District Court neglected to address the validity of that delegation under § 264(c)(1). That should have been done first. The invalidity of § 264(c)(1) obviates any need for its construction. This Court has stated "a court may consider an issue "antecedent to . . . and ultimately dispositive of" the dispute before it, even an issue the parties fail to identify and brief." *U.S. National Bank of Oregon v. Independent Insurance Agents*, 508 U.S. 439, 447 (1993) ("USNB") (citations omitted).

Amici believe that § 264(c)(1) is unconstitutional and delegated no authority to the Secretary. By ignoring the validity of § 264(c)(1), the courts below have issued advisory opinions regarding regulations issued pursuant to a "non-existent" act of Congress. Section 264(c)(1) is unconstitutional because it (1) violates the Bicameral and Presentment Clauses; (2) violates the Non-Delegation Doctrine[9]; and (3) exceeds the powers granted to Congress under the Constitution. As discussed below, Congress never enacted legislation regarding the standards for privacy of individually identifiable health information. It merely directed the Secretary to make legislative recommendations. Congressional authority to issue the Regulations is, in fact, a null set.

It has been a long-standing principle of statutory construction that when a court is asked to construe a law, it has the authority to determine if that law exists.

> " . . . [A] court properly asked to construe a law has the constitutional power to determine whether the law exists,

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[9] Although the Secretary argued to both courts below that he received a broad delegation of authority from Congress to promulgate privacy standards, he contended it was inappropriate for the Third Circuit to address *Amici's* non-delegation argument. Brief for Appellee, 35n.8. In response to the Secretary's contention, *Amici* made a motion to file a reply brief pursuant to Fed. R. App. P. 29 (b&f) regarding the applicability of the Non-Delegation Doctrine. Motion of Guenter L. Spanknebel, M.D. [*et al.*], as *Amici Curiae*, to File Reply Brief. The Third Circuit granted the motion. Order, dated March 4, 2005).

> cf. *Cohens v. Virginia*, 6 Wheat. 264, 405 (1821) ("[I]f, in any controversy depending in a court, the cause should depend on the validity of such a law, that would be a case arising under the constitution, to which the judicial power of the United States would extend") (Marshall, C.J.). The contrary conclusion would permit litigants, by agreeing on the legal issue presented, to extract the opinion of a court on hypothetical Acts of Congress or dubious constitutional principles, an opinion that would be difficult to characterize as anything but advisory."

USNB, 508 U.S. at 446-447.

Under Supreme Court precedent, "[w]hen an issue or claim is properly before the court, the court is not limited to the particular legal theories advanced by the parties, but rather retains the independent power to identify and *apply the proper construction of governing law*." *Kamen v. Kemper Financial Services, Inc.*, 500 U.S. 90, 99 (1991) (emphasis added); *USNB* 508 U.S. at 446 (*quoting Kamen*). The failure of litigants to argue the legal issues correctly does not render an appellate court powerless to address those issues properly.

> "Appellate review does not consist of supine submission to erroneous legal concepts even though none of the parties declaimed the applicable law below. [An appellate court's] duty is to enunciate the law on the record facts. Neither the parties nor the trial judge, by agreement or passivity, can force us to abdicate our appellate responsibility."

Forshey v. Principi, 284 F.3d 1335, 1357 n.20 (Fed. Cir.), *cert. denied*, 537 U.S. 823 (2002) *quoting Empire Life Ins. Co. of Am. v. Valdak Corp.*, 468 F.2d 330, 334 (5th Cir. 1972). Indeed, appellate review of the proper law prevents misapplication of the law, injustice, and the construction of hypothetical laws.

A. Section 264(c)(1) Unconstitutionally Limits the Time of Congress to Pass a Law

Since our nation was founded, a "single, finely wrought and exhaustively considered, procedure" has been used to enact federal legislation. *Immigration and Naturalization Service v. Chadha*, 462 U.S. 919, 951 (1983). That procedure is specified in the Constitution's Bicameral and Presentment Clauses. Strict compliance with that procedure is required. When Congress delegates its lawmaking function to another branch or independent agency it may not legislatively alter the Presentment Clause. If it does, the delegation is unconstitutional. For example, the legislative veto and line item veto were declared unconstitutional. *Id.* at 959; *Clinton v. City of New York*, 524 U.S. 417 (1998) (Stevens,J.). Similarly, when Congress conditions the delegation of its lawmaking function upon the restriction of its own time to consider legislation, it alters that legislative procedure. Section 264(c)(1) contains such an alteration.

The Bicameral and Presentment Clauses require passage of exactly the same text by both Houses and presentment to the President. *Clinton*, 524 U.S. at 448. Those procedures may not be statutorily supplemented or modified. They may be altered only by a constitutional amendment. *Clinton*, 524 U.S. at 449; *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 837 (1995) (Stevens, J.); *Oregon v. Mitchell*, 400 U.S. 112, 128 (1970). Section 264(c)(1) alters the procedure without ratifying a constitutional amendment in accordance with Article V. Pursuant to § 264(c)(1), once three years had elapsed without passage of new health privacy legislation, the Secretary had six months to regulate (unless the House, Senate and the President had agreed otherwise). Furthermore, without § 264(c)(1), the Secretary may not regulate health privacy unless the House, Senate and President agree on health privacy legislation.

A law such as §264(c)(1), which completely delegates legislative responsibility to an executive department or independent agency, violates the Constitution's letter and spirit. The abdication of congressional responsibility encouraged by § 264(c)(1) is philosophically at odds with the Constitution. *Clinton*, 524 U.S. at 452 (Kennedy, J., concurring) ("Abdication of responsibility is not part of the constitutional design"). Section 264(c)(1) turned delegation on its head and conditioned rulemaking authority solely upon the failure of Congress to take action between two specified dates. It allowed Congress to avoid tough decisions. As a result, the scope of delegation was set by the Secretary rather than by agreement of both Houses and the President.

Although not every action taken by Congress is subject to the bicameralism and presentment requirements, those requirements must be met when Congress exercises legislative power. Whether particular actions are an "exercise of legislative power depends not on their form but upon 'whether they contain matter which is properly to be regarded as legislative in its character and effect.'" *Chadha*, 462 U.S. at 952 (citation omitted).

The legislative character of an action may be established by an examination of the congressional action that it supplants. This "Supplantation Principle" was used to analyze the constitutionality of the legislative veto in *Chadha*. *Id.* at 952 ("The legislative character of the one-House veto in these cases is confirmed by the character of the congressional action it supplants"). This principle should be extended to apply to actions undertaken by independent agencies and executive departments. There is no reason to limit application of this principle to evaluating congressional exercises of legislative power.

The Regulations are legislative in both character and effect in two ways. First, by its own terms, § 264(c)(1) equates the Regulations to legislation. The alleged authority of the Sec-

retary to promulgate regulations arose only after Congress failed to pass legislation governing standards with respect to the privacy of IIHI within 36 months of the enactment of HIPAA. Second, the Regulations had the purpose and effect of altering the rights, duties, and relations of persons, including patients, providers, health care clearinghouses, health plans, HHS, Office of Civil Rights and others, all outside of Congress. Section 264(c)(1)("Such regulations shall address at least the subjects described in subsection (b)").

Subsections "a" and "b" also demonstrate the legislative character and effect of the Regulations. Subsections "a" and "b" direct the Secretary to make legislative recommendations regarding privacy of IIHI. They set a limited agenda for the Secretary: to make recommendations for future legislation. The difficult policy choices regarding rights, procedures, and uses and disclosure of IIHI were left to Congress. Subsection "a" explicitly directed the Secretary to submit "detailed recommendations on standards with respect to the privacy of [IIHI]." Those recommendations were to be received by a Senate Committee and a House Committee. As used, the word "recommendations" contemplated future congressional action. In the context of § 264, "recommendations" were sought to enable Congress to propose and possibly enact future legislation. The subjects contained in § 264(b) are legislative in nature and include the rights an individual should have, § 264(b)(1), the procedures for exercising those rights, § 264(b)(2), and the determination of permitted "uses and disclosures", § 264(b)(3). If Congress had enacted the recommendations with respect to those rights, everyone in the United States would have been affected. Similarly, the Regulations affect everyone in the United States—people and parties outside Congress.

The language seeking recommendations from the Secretary set forth in Subsections "a", "b", and "d" suggests that Congress was writing on a blank slate. It needed to be better informed before legislating. Under Subsections "a", "b", and

"d", Congress explicitly sought recommendations from the Secretary regarding those standards because it had not yet made any policy determination or value judgment regarding the standards for privacy of IIHI when it enacted HIPAA. Marci Hamilton, *Representation and NonDelegation: Back to Basics*, 20 Cardozo L. Rev. 807, 820 (1999)("The legislature holds primary responsibility to make the national policy choices, and the President may not take on those choices"). Congress had not balanced the interests of various constituencies regarding that subject matter.[10] However, Congress had recognized that it needed further advice. Consequently, HHS rulemaking authority under §264(c)(1) was equated to legislation and *carved-out* from the remainder of §1173 rulemaking authority.[11]

B. Congress Defectively Delegated Authority to the Secretary

Congress may only delegate power it received from the People. This principle adds a fourth component to the three-pronged "intelligible principles" test. It is derived from the

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[10] Institutionally, Congress is better able to balance multiple viewpoints than a single agency or department. *See*, Hamilton, 20 Cardozo L.Rev. at 814 ("The legislative branch serves the people by filtering the factions in the society and distilling those laws that will best serve the nation . . . [P]ositions must be funneled through a large number of ports before becoming governing law . . . [Congress] is capable of reaching more nuanced compromises on national issues"). In contrast, when lawmaking is delegated to the President, there is only one port of entry, one viewpoint, albeit representing the entire nation. When lawmaking is delegated to an agency or executive department, the viewpoint is even narrower and without electoral accountability. *Id.* at 819-21. It is evident that Congress and not the Secretary should be the filter setting national policy regarding health privacy. The Secretary received over 60,000 comments regarding the Original and Modified Regulations, 67 Fed. Reg. at 53182-83.

[11] Section 1173 authorized the Secretary to issue uniform national standards regarding: transactions, unique health identifiers, code sets, security and electronic signatures. In conference, privacy of IIHI had been moved out of §1173. 65 Fed Reg. at 82469-70.

understanding that the federal government is one of enumerated powers and that a principal may not delegate authority it lacks.

1. *The 104th Congress Could Not Have Delegated Its Authority Beyond the End of Its Term*

Since our nation's first days, "[e]very law enacted by Congress must be based on one or more of its powers enumerated in the Constitution." *United States v. Morrison*, 529 U.S. 598, 607 (2000); *McCulloch v. Maryland*, 4 Wheat. (17 U.S.) 316, 405 (1819). Those powers are constrained by the Constitution's procedural requirements, *see e.g.*, U.S. CONST. art. I, § 7, cl.2, and substantive requirements, *see e.g.* U.S. CONST. art. I, § 9. Another constraint is provided by the temporal limit on the congressional franchise.

The President and members of the Senate and members of the House represent different geographic constituencies, have different modes of election, and have different requirements for holding office. U.S. CONST. art. I, §§ 2 & 3, U.S. CONST. art. II, § 1 and U.S. CONST. amend. XVII. The Constitution further diffuses power by limiting the terms of the President and members of the Senate and House and by making those terms of different lengths, *i.e.* they have different temporal mandates. Senators are elected for six years. U.S. CONST. art. I, § 3, cls. 1&2 and U.S. CONST. amend. XVII. The President is elected for four years. U.S. CONST. art. II, § 1, cl. 1. Members of the House of Representatives are elected for two years. U.S. CONST. art. I, §2, cl. 1. The authority of each Representative, each Senator and the President does not extend beyond the expiration of his or her term in office, respectively.[12] Any extension of authority beyond the end of those terms would unconstitutionally transfer from the "people" the power of the people to choose their own repre-

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[12] *See* Joseph Story, *Commentaries on the Constitution of the United States* (Carolina Academic Press) Book III § 263.

sentatives.[13] One commentator characterized the holding of elective offices as a "temporary lease" from the nation's citizens. Alan Morrison, *A Non-Power Looks at Separation of Powers*, 79 Geo. L.J. 281, 282 (1990). Expressed in real estate terms, the Constitution does not allow "holdovers".

When Congress "delegates" its power to "make law"[14], the delegation must occur before the congressional term ends. The reasoning is simple. A principal may delegate to its agent only the authority within its possession. A principal may not delegate authority that it does not have. Each House and Senate member loses all authority from his or her constituents at term-end. Consequently, the end of a congressional term ends **subsequent legislative actions** by that Congress. Similarly, the President has no authority to sign or veto legislation once his or her term expires. If Congress, as principal, cannot exercise its legislative power, then an agent of that Congress may not exercise that power.

Under §264(c)(1), the 104th Congress did not attempt to delegate its authority during the remaining four-plus months of its term or even during the 24 months of the 105th Congress. It was not until the eighth month of the 106th Congress, *i.e.* 36 months after the enactment of HIPAA, that the Secretary could issue the Regulations. However, the Regulations could never have been issued if Congress had enacted health privacy legislation during the intervening 36 months. Once the 105th Congress began, the 104th Congress had no power. Beginning in January 1997, the 104th Congress had

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[13] George Washington said: "The power under the Constitution will always be in the People. *It is entrusted* for certain defined purposes, *and for a certain limited period, to representatives of their own chusing*; and whenever it is executed contrary to their Interest . . . their Servants can, and undoubtedly will be [ ] recalled." *Thornton*, 514 U.S. at 814n.26 (emphasis added)(citations omitted).

[14] The power to "make law" stands in contrast to the power to "fill-in details" or otherwise "execute" legislation. *See, Loving v. United States*, 517 U.S. 748, 771 (1996) (Kennedy, J.).

no power to "make law" with respect to health privacy standards or anything else. Consequently, the agent of the 104th Congress, the Secretary, lacked that power as well.

2. *Congress Provided No Policy or Boundary to Limit the Secretary's Authority*

Under the "intelligible principles" test, a delegation is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Mistretta v. United States*, 488 U.S. 361, 372-373 (1989)(citation omitted). A delegation is always subject to the legislation that authorized it. *Chadha*, 462 U.S. at 953-54 n.16.

It has been suggested that delegation to administrative agencies leaves a gaping hole in the Constitution's balanced structure of checks and balances because agencies are prone to be arbitrary and unaccountable. "The nondelegation doctrine in this scenario is crucial to liberty, because it prohibits general lawmaking from occurring in a structure both capable of arbitrary action and removed from the national scrutiny to which both Congress and the President are exposed by the constitutional structure." Hamilton, 20 Cardozo L. Rev. at 821.

Section 264(c)(1) fails to meet two of the "intelligible principle" criteria. First, there is no clearly delineated general policy. Second, there is no boundary on the delegated authority.

Neither the general policy statement contained in the Preamble to HIPAA nor the policy statement articulated as § 261 of the Administrative Simplification provisions of HIPAA "clearly delineates" a general policy that is applicable to the privacy of IIHI.

The Preamble provides that HIPAA is:

> "[a]n Act to amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health

> care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes."

110 Stat. at 1936. None of these stated purposes refer to privacy of IIHI.

Section 261, contains a statement of the purpose of subtitle F of HIPAA. 110 Stat. at 2021 (not codified but *appears* at 42 U.S.C. § 1320d note). The language at the end of § 261 (*i.e.* "through the establishment of standards and requirements for the electronic transmission of certain health information") does not provide the Secretary with authority to issue standards with respect to the privacy of IIHI. A fair reading of § 261's language points to § 1173, which is entitled "STANDARDS TO ENABLE ELECTRONIC EXCHANGE". It does not point to § 264, which is entitled "RECOMMENDATIONS WITH RESPECT TO PRIVACY OF CERTAIN HEALTH INFORMATION." Section 264 directed the Secretary to make recommendations. It did not direct the Secretary to establish any standard with respect to privacy of IIHI upon enactment. The only authority to issue such standards was contingent authority if Congress failed to enact legislation. The policy and purpose with respect to privacy of IIHI were to be determined by later legislation. HIPAA contained no policy or purpose with respect to privacy of IIHI. *But see South Carolina Medical Association v. Thompson*, 327 F.3d 346, 351 (4th Cir.), *cert. denied*, 540 U.S. 981(2003) (finding a "general policy" of privacy).[15]

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[15] Section 264(c)(1) and the Regulations are inconsistent with a policy of privacy. They apply only to covered entities and do not apply to other individuals and entities that wrongfully obtain IIHI. Exec. Order No. 13181 *reprinted in* 42 U.S.C. §1320d-2 notes. Furthermore, the Regulations do not apply to all private medical information but only to IIHI that is within the scope of §1173. Section 264(c)(1). If privacy were truly the policy, the Secretary would not have been able to reduce confidential-

The phrase "shall address at least" is used both to list the subjects of legislative recommendations to be submitted by the Secretary and to list the subjects of rulemaking authority to be delegated if Congress failed to pass legislation by the statutory deadline. The use of that phrase removed all limits on the Secretary's authority. In *A.L.A. Schechter Poultry Corporation v. United States*, the Supreme Court struck down, as overly broad, a delegation that merely affected all industries. 295 U.S. 495 (1935). The delegation in §264(c)(1) is much broader. Its impact is not limited to the healthcare industry or even to all industries. It affects everyone. Its impact is pervasive.

Section 264(c)(1) contains no boundaries to determine whether the Secretary has exceeded the authority granted by Congress. *See Yakus v. United States*, 321 U.S. 414, 423-424 (1944); *Chadha*, 462 U.S. at 953. It specifies only a minimal set of subjects to be recommended to Congress and a minimal set of subjects to be included in future regulations if Congress did not enact such legislation by the deadline. Although the Secretary was required to "address at least" the three subjects specified in §264(b), there are no limits or constraints upon those subjects. Potentially, the Secretary could have addressed an infinite number of subjects[16] and had unbounded discretion with respect to each subject that he or she did address. In *Whitman v. American Trucking Associations, Inc.*, the Supreme Court said, "[t]he very choice of which portion of the power to exercise—that is to say, the prescription of the standard that Congress had omitted—would *itself* be an exercise of the forbidden legislative authority." 531 U.S. 457,

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ity from the Hippocratic standard practiced by physicians throughout our nation's history.

[16] The meaning of the words "at least" is unambiguous. In mathematical terms, those words mean "greater than or equal to". There is no upper limit. Under the Plain Meaning Rule, the Court must construe the words as written. *Connecticut National Bank v. Germain*, 503 U.S. 249, 253-54 (1992) (Thomas, J.).

473 (2001) (Scalia, J.). The Secretary has exercised such forbidden legislative authority.

C. The Constitution Does Not Give Congress Authority to Impair a Physician's Confidentiality Obligations

It is black letter law that "the powers of the legislature are defined and limited." *Marbury v. Madison*, 1 Cranch (5 U.S.) 137, 176 (1803) (Marshall,C.J.). *See also*, The Federalist, No. 45, at 292 (Madison) (Clinton Rossiter, ed. 1961) ("The powers delegated by the proposed Constitution to the federal government are few and defined").

According to the Constitution, the states are prohibited from changing or "impairing" contractual obligations. U.S. CONST. art. I, § 10, cl. 1 ("No State shall . . . pass any . . . Law impairing the Obligation of Contracts. . . ."). Here, no state law is at issue. Rather, federal law (*i.e.* §264(c)(1) and the Regulations) acts to impair confidentiality obligations from physicians to patients.[17] No power of Congress to impair a contractual obligation was enumerated in the Constitution other than the Bankruptcy Clause. U.S. CONST. art. I, § 8, cl. 4.

> While section 10 of Article I of the Constitution is directed to the states alone, we think it nevertheless states the policy of the founders of the Government on the question of impairing the obligation of contracts and that any Act of the national legislature that does impair the obligation of contracts is contrary to that policy and not

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[17] Typically, a contract is formed when a patient receives care from a physician. The patient promises to pay or have a third party pay. The physician promises to diagnose and treat the patient. The physician also promises to keep the confidences of his or her patients. Dr. Benjamin Rush, a signer of the Declaration of Independence said: "[t]he most important contract that can be made, is that which takes place between a sick man and his doctor. The subject is human life. . ." American College of Physicians, Medicine in Quotations Online *at* www.acponline.org/cgi-bin/medquotes.pl (citations omitted).

> within the powers delegated to the National Government, except in specific cases, such as bankruptcy.

Johnson v. U.S., 79 F.Supp. 208 (Ct. Cl. 1948).[18] The lack of congressional power to impair contractual obligations is also confirmed by the need to include a provision in the Fourteenth Amendment in order to extinguish debts and obligations incurred in aid of the confederacy. U.S. CONST. amend. XIV, § 4.

Without a constitutional amendment authorizing Congress to enact laws impairing the obligation of contracts, § 264(c)(1) and the Regulations may not impair a physician's obligation to keep a patient's confidences. This is as true today as it was 219 years ago.[19]

CONCLUSION

For the foregoing reasons, the Court should grant *certiorari* and ultimately declare § 264(c)(1) unconstitutional and the Regulations void.

Respectfully submitted,

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[18] The impairment of physicians' obligations may not be justified by nor derived from the Constitution's other provisions. *But see, Continental Illinois National Bank and Trust Company of Chicago v. Chicago, Rock Island & Pacific Railway Company*, 294 U.S. 648, 680-81 (1935).

[19] The Framers understood the importance of a physician's confidentiality obligation. In fact, one key Framer, Dr. Josiah Bartlett, was founder and first president of the New Hampshire Medical Society. As New Hampshire's representative to the Continental Congress, he cast the first vote for the Declaration of Independence. He also cast the first vote for the Articles of Confederation. With the help and influence of Dr. Bartlett during its ratification convention, New Hampshire became the ninth state to ratify the Constitution, triggering the formation of the United States under Article VII. U.S. CONST. art. VII. Signers of the Declaration: Biographical Sketches (Josiah Bartlett) *at* www.cr.nps.gov/history/online_books/declaration/bio3.htm.